K050771 1/3

APR 8 2005

510(k) SUMMARY

Lupine Loop Anchor

Submitter's Name and Address:	DePuy Mitek a Johnson & Johnson company 249 Vanderbilt Avenue Norwood, MA 02062
Contact Person	Denise Luciano Senior Regulatory Affairs Specialist DePuy Mitek a Johnson & Johnson company 249 Vanderbilt Avenue Norwood, MA 02062 Telephone: 781-251-2794 Facsimile: 781-278-9578 e-mail: dluciano@dpyus.jnj.com
Name of Medical Device	Classification Name: Screw, Fixation, Bone Staple Common/Usual Name: Appliance for reconstruction of soft tissue to bone Proprietary Name: Lupine Loop System
Substantial Equivalence	Lupine Loop Anchor is substantially equivalent to: Panalok Loop Anchor, K040827, manufactured by DePuy Mitek.
Device Classification	Bone anchors/screws are classified by the FDA as Class II Medical Devices under the generic category of Single/Multiple component metallic bone fixation appliances and accessories. Lupine Loop Anchor Systems carry FDA product code MAI, and is classified as Biodegradeable soft tissue fastener under 21 CFR 888.3030.
Device Description	Lupine Loop System is a preloaded, absorbable disposable suture anchor/ inserter assembly designed to allow soft tissue repair to bone. The absorbable polylactic acid (PLA) anchor is an identical anchor as that of the Panalok Loop Anchor in design, configuration and dimensions. The absorbable anchor is a one piece suture anchor

K050771/3

constructed of molded Poly (L-lactide) polymer. The anchor system may be sold with Ethibond Suture (NDA 17-804 and 17-809), Panacryl Suture (K964345), or Orthocord Suture (K040004 and K043298).

Indications for Use

The Lupine Loop Anchor System is indicated for use in soft tissue to bone fixation in association with adequate postoperative immobilization as follows:

OPEN PROCEDURES SHOULDER
1. Bankart repair
2. SLAP lesion repair
3. Rotator cuff repair
4a. Capsule shift/capsulo-labral reconstruction, at the anterior glenoid rim site
4b. Capsule shift/capsulo-labral reconstruction at the lesser tuberosity of the humerus
5. Biceps tenodesis
6. Acromio-clavicular separation
7. Deltoid repair

ELBOW
1. Biceps tendon reattachment
2. Tennis elbow repair

ANKLE
1. Achilles tendon repair/reconstruction
2. Lateral stabilization
3. Medial stabilization at the medial talus site
Foot: Hallux Valgus reconstruction
4. Midfoot reconstruction

KNEE
1. Medial collateral ligament repair
2. Lateral collateral ligament repair
3. Joint capsule closure to anterior proximal tibia
4. Posterior oblique ligament or joint capsule to tibia repair
5. Extra capsular reconstruction / ITB tenodesis
6. Patellar ligament and tendon avulsion repairs.

ARTHROSCOPIC PROCEDURES SHOULDER
1. Bankart repair
2. SLAP lesion repair
3. Rotator cuff repair
4. Capsule shift repair (glenoid rim)

K050771
3/3

Safety and Performance	The determination of substantial equivalence for this device was based on a detailed device description, and conformance to consensus and voluntary standards. Bench testing was performed demonstrating that the ORTHOCORD suture conformed to the USP monograph for absorbable sutures, and the suture compatibility and deployment met predetermined acceptance criteria. Based on the indications for use, technological characteristics, and comparison to predicate devices, the Lupine Loop System has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 8 2005

Ms. Denise Luciano
Senior Regulatory Affairs Specialist
DePuy Mitek
249 Vanderbilt Avenue
Norwood, Massachusetts 02062

Re: K050771
Trade/Device Name: Lupine Loop System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/ multiple component metallic bone fixation appliances
Regulatory Class: II
Product Code: GAM, MAI
Dated: March 24, 2005
Received: March 25, 2005

Dear Ms. Luciano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050771/2

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Names: Lupine Loop System

Indications for Use:

The Lupine Loop Anchor System is indicated for use in soft tissue to bone fixation in association with adequate postoperative immobilization as follows:

OPEN PROCEDURES SHOULDER
1. Bankart repair
2. SLAP lesion repair
3. Rotator cuff repair
4a. Capsule shift/capsulo-labral reconstruction, at the anterior glenoid rim site
4b. Capsule shift/capsulo-labral reconstruction at the lesser tuberosity of the humerus
5. Biceps tenodesis
6. Acromio-clavicular separation
7. Deltoid repair

ELBOW
1. Biceps tendon reattachment
2. Tennis elbow repair

ANKLE
1. Achilles tendon repair/reconstruction
2. Lateral stabilization
3. Medial stabilization at the medial talus site
Foot: Hallux Valgus reconstruction
4. Midfoot reconstruction

KNEE
1. Medial collateral ligament repair
2. Lateral collateral ligament repair
3. Joint capsule closure to anterior proximal tibia
4. Posterior oblique ligament or joint capsule to tibia repair
5. Extra capsular reconstruction / ITB tenodesis
6. Patellar ligament and tendon avulsion repairs.

K050771/2

ARTHROSCOPIC PROCEDURES SHOULDER
1. Bankart repair
2. SLAP lesion repair
3. Rotator cuff repair
4. Capsule shift repair (glenoid rim)

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

rative

K050771